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**Subject: US SN 09/980,962**

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**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Mark Laurence Brader

Serial No.: 09/980,962

Filed: June 15, 2000

For: PROTAMINE-FREE INSOLUBLE ACYLATED  
INSULIN COMPOSITIONS

Docket No.: X-12785

Confirmation No.  
3515Group Art Unit:  
1654Examiner:  
Roy Teller**RESPONSE TO UNITY OF INVENTION OBJECTION**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated September 16, 2003, Applicant provides the following remarks.

***I. The Unity Of Invention Objection***

In the Office Action, the Examiner restricted the claims into the following two groups:

Group I: claims 1-4, 6, 7 and 9-20; and

Group II: claims 5 and 21-28.

The Examiner states that the claims lack unity of invention because, in the Examiner's opinion, they do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. In the Examiner's opinion, "the special technical feature (as defined by the first presented composition) is Ultralente-like crystals, which is a known compound . . . ." The Examiner cited WO 98/42367 and WO 98/42368 as prior art, and stated that "the special technical feature which links the claims does not provide a contribution over the art, so unity of invention is lacking."

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## ***II. The Unity Of Invention Objection Must Be Withdrawn***

Applicant respectfully disagrees with the unity of invention objection, for the following reasons. First, the claims are grouped improperly. Second, unity of invention exists, because a special technical feature is common to independent claims 1 and 5.

### ***A. Proper Claim Grouping And Election***

Applicant elects, with traverse, Group I, claims 1-4, 6, 7 and 9-20. However, if the Examiner maintains the unity of invention objection, Applicant respectfully requests that claims 1-4, 7, 9, 10, 13-19 and 21-23 be examined together.

Applicant respectfully points out that the claims were grouped improperly in the Office Action. Claims 1-28 are pending in the present application. Of these, claims 1 and 5 are independent claims. Claims 2-4, 6, 7 and 9-28 are dependent claims, and claims 13-18 are multiple dependent claims. When one examines the claims and takes into account the various claim dependencies, one finds that the claims should be grouped as follows:

claims 1-4, 7, 9, 10, 13-19 and 21-23; and

claims 5, 6, 11-18, 20 and 24-28.

Even if the unity of invention objection is maintained, Applicant respectfully requests that claims 1-4, 7, 9, 10, 13-19 and 21-23 be examined together.

### ***B. Unity Of Invention Exists***

The expression "special technical features" is defined in PCT Rule 13.2 as meaning "those technical features that define the contribution which each of the inventions, considered as a whole, makes over the prior art." See MPEP Administrative Instructions Under The PCT, Annex B, Part 1, page AI-63.

Applicant respectfully points out that, in the Office Action, the Examiner failed to take into account the contribution of the invention of independent claims 1 and 5 over the prior art. By characterizing the invention as "Ultralente-like crystals," see page 3 of the Office Action, the Examiner relied only on the claim preamble, but ignored the rest of the language of claims 1 and 5. Claims 1 and 5 provide:

1. Ultralente-like crystals, comprising:

- a) a derivatized human insulin or derivatized human insulin analog formed by derivatizing human insulin or a human insulin analog with a saturated, straight-chain fatty acid having from 4 to 16 carbon atoms such that the fatty acid forms an amide bond with the  $\epsilon$ -amino group of the B29-lysine of human insulin or a human insulin analog; and
- b) a divalent metal cation.

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5. Ultralente-like crystals, comprising:
- a) a protein selected from the group consisting of insulin and insulin analogs;
  - b) a derivatized human insulin or derivatized human insulin analog formed by derivatizing human insulin or a human insulin analog with a saturated, straight-chain fatty acid having from 4 to 16 carbon atoms such that the fatty acid forms an amide bond with the  $\epsilon$ -amino group of the B29-lysine of human insulin or a human insulin analog; and
  - c) a divalent metal cation.

Although claim 5 contains a limitation that claim 1 does not contain, claims 1 and 5 have in common two special technical features. Each claim recites "a derivatized human insulin or derivatized human insulin analog that is formed by derivatizing human insulin or a human insulin analog with a saturated, straight-chain fatty acid having from 4 to 16 carbon atoms such that the fatty acid forms an amide bond with the  $\epsilon$ -amino group of the B29-lysine of human insulin or a human insulin analog." And each claim recites "a divalent cation."

It is instructive to refer to the unity invention examples in the MPEP, Part 2, Annex B. The most relevant example is Example 12 at pages AI-69 to AI-70. Example 12 provides:

Example 12

Claim 1: A display with features A + B.

Claim 2: A display according to claim 1 with additional feature C.

Claim 3: A display with features A + B with additional feature D.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is features A + B.

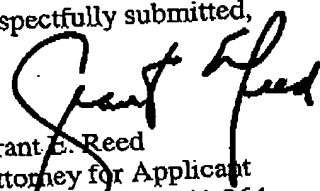
Claims 1 and 5 of the present application are directly analogous to claims 1 and 2, respectively, of Example 12. In claims 1 and 5 of the present application, the term "Ultralente-like crystals" corresponds to the term "display" in Example 12. In claims 1 and 5 of the present application, the term "a derivatized human insulin or derivatized human insulin analog . . ." corresponds to the term "feature A" in Example 12. In claims 1 and 5 of the present application, the term "a divalent metal cation" corresponds to the term "feature B" in Example 12. And in claim 5 of the present application, the term "a protein selected from the group consisting of insulin and insulin analogs" corresponds to the term "feature C" in Example 12.

Thus, unity of invention exists for independent claims 1 and 5 in the present application. Unity of invention also exists for the dependent claims. See MPEP at page AI-63, part (c)(i) ("[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims.").

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Applicant respectfully requests that the unity of invention objection be reconsidered and withdrawn.

Respectfully submitted,

  
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